SUMMARY OF THE QUALITY SYSTEMS COMMITTEE TELECONFERENCE JUNE 24, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on June 24, 1999, at 1 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of U.S. Environmental Protection Agency (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues is currently empty (Attachment C). Attachment D presents the QS Committee approach to handling comments, comment acknowledgment form letter, guiding principles for reviewing comments and the standard and commenter template. Attachment E contains the QS Committee's response to comments addressed during this meeting. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.13 of the standard. However, to avoid confusion within NELAC, since version 5.10.7 is the version provided for NELAC 5 voting, 5.10.13 is only being circulated within the QS Committee at this time (not attached to these minutes and will not be posted on the NELAC Website). *The purpose of the meeting was to discuss whole effluent toxicity issues, the glossary, and additional comments received by the committee.*

FUTURE PLANS

The future plans for the QS Committee are to eliminate redundancies in the chapter and to expand the demonstration of capability criteria to include toxicity testing.

TOPICS OF DISCUSSION

Glossary

The QS Committee reviewed the combined glossary revisions that Ms. Sheila Meyers and Dr. Tom McAninch of the Program Policy and Structure Committee addressed. The QS Committee's approach to the glossary was to focus on definitions that are part of Chapter 5. Refer to Attachment E for the glossary changes, most of which were minor.

The combined glossary will become part of Chapter 1, Program Policy and Structure.

Whole Effluent Toxicity (W.E.T.) Testing

The committee reviewed Dr. Peter DeLisle's responses to comments from the Virginia NELAC Workgroup that relate to W.E.T. testing. The responses to these comments are not attached to this document as the file was not readable.

In Section D.2, the term *whole effluent toxicity* should be replaced with a more generic term such as *toxicity, toxicity testing, or toxicology*, as appropriate, because soils and sediments testing methods are increasingly being used and this section should apply to these methods as well as W.E.T.

Section D.2.1.a.4.i

It was pointed out that the method manual doesn't specify a criterion that a control population of *Ceriodaphinia* shall contain no more than 20% male. The W.E.T. subcommittee that developed this section tried to identify things not in the methods that should be included in Chapter 5 and this criterion is widely accepted among aquatic toxicologists.

Wisconsin Department of Natural Resources

The committee reviewed the initial responses to the comments from the Wisconsin Department of Natural Resources. Refer to Attachment E for the detailed comments and responses.

Section 5.9.4.2.2.d:

Language was added to this section requiring that the continuing calibration verification records clearly tie the continuing verification data to the initial instrument calibration.

The definition of *Internal Standard* was changed to: a known amount of standard added to a test portion of a sample and carried through the ~~entire measurement~~ determinative procedures of the measurement ~~process~~ as a reference for ~~evaluating~~ determining the target analyst/s concentration and for evaluating ~~and controlling~~ the precision and bias of the applied analytical test method.

References to *matrix spike* and *matrix spike duplicate* were added to the definition of *spike*

Department of Defense

The responses to these comments are presented in Attachment E. The comments are not attached as this file was not readable.

Section 5.5.3. 1-5:

The requirements should include that a time frame must be identified in the laboratory's Quality Manual and/or standard operating procedures (SOPs). One approach is to require a plan for corrective action within a certain period of time after the need for corrective action is identified.

Section 5.5.3.2:

A managerial review, which is the title of section 5.5.3.2, is not the same as an audit nor a Management Systems Review. Therefore, the title of Section 5.5.3 will be changed to *Audits and Reviews* so that it covers Section 5.5.3.2.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
JUNE 24, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Slayton to forward comments from Mr. Jerry Parr to QS Committee members.	
2	Propose to the Program Policy and Structure Committee that the definition of internal standard should be reworded.	After NELAC V
3.	Mr. Slayton to update Chapter 5 from revision 5.10.12 to 5.10.13 and circulate within the committee.	After NELAC V

Attachment B

PARTICIPANTS
Quality Systems Committee
June 17, 1999

Name	Affiliation	Phone Numbers
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Ms. Sheila Meyers	Texas Natural Resource Conservation Commission	T: 512-239-0425 F: 512-239-6307 E: smeyers@tnrcc.state.tx.us
Mr. Jeff Nielson	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
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Attachment C

PARKING LOT ITEMS/ISSUES
QUALITY SYSTEMS COMMITTEE
JUNE 24, 1999

Items/issues will remain in the Parking Lot until they are completed.

(There are no items/issues in the Parking Lot at this time.)

Attachment D

ACKNOWLEDGMENT LETTER, REVIEW GUIDELINES, AND COMMENTER TEMPLATE
QUALITY SYSTEMS COMMITTEE
JUNE 24, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,
Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled in by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in by Commentor)** **New Wording for Standard (To Be Filled in by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**

Attachment E

RESPONSES TO COMMENTS
Quality Systems Committee
June 24, 1999

Final Glossary Changes

1. **Accreditation:** The process by which an agency or organization evaluates and recognizes a program of study, institution or laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

   Rationale: - PP&S wanted laboratory in place of "program of study or an institution." We agreed on no deletions but adding "laboratory".

2. **Accrediting Authority:** The Territorial, State, Federal agency or tribes having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

   Rationale: - This definition is a combination of QS and PP&S. The last sentence of the definition was deleted and restated in the first sentence. " and tribes" was changed to "or tribes" and was added from the QS definition.

3. **Analytical Reagent (AR) Grade:** QS definition unchanged.

   Rationale: PP&S deleted their definition. I requested that the definition stay.

4. **Assessor Body**: The organization that actually executes the accreditation process, i.e., receives and reviews accreditation applications, reviews QA documents, reviews proficiency testing results, performs on-site assessment, etc., whether EPA, the State or contracted private party.

   Rationale: "performs on-site assessment" replaces "surveys the site". Sentence improvement. The other examples are not necessarily things that have to be performed on site.

5. **Assessor:** One who perform on-site assessments of accrediting authorities and laboratories capability and capacity for meeting NELAC requirements by examining the records and other physical evidence fro each one of the tests fro which accreditation has been requested..

   Rationale: PP&S added "assessments" was added in place of "evaluation" and "accrediting authorities". Tom and I agreed that assessors perform assessments!

6. **Technical Analyst** - changed to Analyst by PP&S committee. Not a QS definition.

7. **Batch**: Definition for QS kept along with new text in line 6, “and/or those samples not requiring preparation.

8. **Calibrate and Calibration**: QS Definitions remain unchanged.

   Rationale: PP&S proposed to delete “calibrate’ and use the definition for calibrate for “calibration”. It was determined that both definitions add value to the standard and will stay.

9. **Calibration Curve**: QS definition remains unchanged.

10. **Chain of Custody**: QS definition per conference call 6/17 added.

    Rationale: This is in full agreement with the PP&S committee.

11. **Confirmation**: QS definition remains unchanged over suggestion made by PP&S.

12. **Data Reduction**: The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation in a more useable ~~useful~~ form.

    Rationale: Agreement that sentence reads better.

13. **Detection Limit**: QS definition stays.

14. **Double Blind Sample**: deleted by PP&S. Not a QS definition.

15. **Environmental Detection Limit**: Deleted by QS committee.

16. **Equipment Blank**: added by PP&S.

17. **Field Blank:** added by PP&S.

18. **Field Duplicate:** New from QS.

19. **Field of Testing:** PP&S added “program” to lines 1 and 2 of the QS definition.

20. **Finding:** PP&S definition left unchanged.

21. **Good laboratory Practices**: Deleted by PP&S since TSCA and FIFRA not included in NELAC.

22. **Holding Times (Maximum Allowable Holding Times**: PP&S definition rejected for addition of “or not compromised.”and QS definition remains unchanged.

    Rationale: addition of the language added confusion.

23. **Initial Demonstration of Capability**: QS definition unchanged.

24. **Interdependent Analytes**: No differences between PP&S, but PT has deleted both interdependent and non-interdependent analytes from standard.

25. **Internal Standard**: Agreed with the PP&S definition to delete "and carried through the entire measurement process" because some internal standards are not carried through the entire process.

26. **Laboratory**: PP&S proposed to delete Note and use other definition. QS definition stays.

27. **Matrix:** QS definition remains unchanged.

28. **Matrix Spike**: PP&S added "a sample" to line 1 of the QS definition.

29. **Media**: New definition added by QS.

30. **Method Blank**: QS definition stays over PP&S.

31. **Must**: QS added "mandatory".

32. **Non-interdependent Analytes**: Definition deleted from PP&S. Not used in PT anymore

33. **Organization for Economic and Cooperative Development (OECD)**: Deleted by PP&S.

34. **Performance Audit**: PP&S added "qualitative and " to line one of the QA definition.

35. **Preservation**: QS definition stays.

36. **Private Laboratory**: New from PP&S.

37. **Quantitation Limits**: QS definition stays.

38. **Raw Data**: QS definition stays.

39. **Sampling** Media: New definition added from QS.

40. **Standardized Reference Material (SRM**): PP&S added "or equivalent organization" and "Standard" becomes "Standardized". Chuck Wibby submitted these comments. We agreed that if anyone should know this, it would be Chuck.

41. **Technical Director**: QS definition stays.

42. **Test Method**: An adoption of a scientific technique fro a specific measurement problem, as documented in a laboratory SOP.

    Rationale: Tom and I agree that the definition by PP&S reads better. Language came from Jerry Parr.

43. **Verification**: QS definition remains. PP&S proposed to delete note.

44. **Work Cell**: New definition from QS.

Department of Defense (DoD)
Comments to National Environmental Laboratory Accreditation Conference (NELAC).
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I. Revision #9
Section 5.5.3. 1-5
Subject: Internal Audits

1. **No change** for 5.5.3. Tools of any type of assessment are considered to be documents, equipment (PCS etc) and procedures used to conduct an audit. These could include things such as: SOPs, QAPPs, and Laboratory QA manuals, PCS, interviewing staff etc., to name a few. This section is not addressing "tools" of internal audits.

2. **No change**. Internal audits may include a variety of things but not all items in 5.5.3 are internal. *Unrelated to their comment - I do believe the section title should be renamed to Audits and Reviews. The Managerial Review is not an audit. This is consistent with ISO 25 and Dis 17025.*

3. **No change.** Technical and Systems audits is only one way of describing internal audits.

4. **Agree (compromise)** That language should be added to standards stating that a time frame for such corrective action will be addressed in each laboratory's QA manual. Suggest language that states that QA manual shall define appropriate time frame for corrective action procedures.

II. Revision #9
Section 5.5.3.4
Subject: Fraud Prevention

1. QS committee members are currently working on "Fraud Prevention" language.

III. Revision #9 & 10.1
Section 5.5.4.b
Subject: Quality Control Procedures

1. **No Change**. Change has been made to standard.

IV. Revision #9 and 10.1
Section 5.9.4.3.a-
Subject: Initial Instrument Calibration/Calibration Verification Bullets 1 - 4

1. **No change**. 15% of true value has been deleted.

2. **No change**. No explanation was given to why the C.V. should be near the mid-point in the initial calibration. QA believe the C.V. should vary in order verify the entire range of the curve.

3. **No change**. Yes, I think everyone agrees that all reported target analytes applicable to the methods should be included in the initial calibration. I think this goes without saying. Apparently this is just a comment.

4. **No change**. There may be other reasons an initial calibration fails other than not being prepared properly. The important thing is if it does, the standard requires that corrective action be initiated.

Section 5.9.4.3.b

1. **No change.** This section allow a minimum of 2 calibration standards but requires an SOP for determining the number of calibration standards. Therefore, standards distributed throughout the range is not necessarily required if all other criteria is met. Criteria. Standard states that "calibration standards must include concentrations at or below the regulatory limit/decision level..."

Section 5.9.4.4.b.3

1. No change. The "how to" for delineation of a nonlinear curve rest with the laboratory.

Section 5.9.4.3.b.4

1. No change. I'm not sure I understand the comment, but the standard states that blanks are not included as a calibration standard.

Section 5.9.4.3.c

1. No change. These standards represent the minimum. If they are not mentioned in the chapter, the default is always the method or any program/regulatory requirements.

Section 5.9.4.3.d

1. **No Change.** Bracketing for C.V. is done at the beginning and ending of each batch. QS does not want to recommend the specification of numerical relationship between the quantitation limit, the reporting limit, and the detection limit, as this relationship may not be appropriate in all situations and may add confusion. Established detection limits must be established and based upon the regulatory limit/decision level.

V. Revision #9

Section 5.9.4.4

Subject: Continuing calibration Verification

1. **No Change**. The comment was the standard(s) for C.V. analysis should be the standard(s). Used for the initial calibration or standard(s) from another source. The QS committee agrees - but puzzled as to what other choice there would be and what suggestive change was wanted.

2. **QS vote on** consideration whether a statement needs to be added that, "All reported target analytes applicable to the methods must be included in the calibration verification if method does not define procedure." I don't feel strongly either way.

3. **Suggest No change but it may not hurt to add more examples other than relative percent difference.** The baseline for comparison for the calibration verification IS the initial calibration (and the original standards). Criteria for the acceptance of a continuing instrument calibration verification must be established - for example relative percent difference. A statement is made in "Initial Instrument

Calibration" that sample results must be quantitated from the initial instrument calibration, therefore **the results of a C.V. do not supersede or override the initial calibration.**

4. **No change.** The standard states that a C.V. must be repeated at the beginning and end of each analytical batch (5.9.4.2.2.b). Revision 10.7.

Section 5.9.4.4.2.b

1. No change. QS and consensus believe that it is more useful information to have the concentrations of the calibration verification standard varied within the established calibration range.

Section 5.9.4.4.2.c

1.**Recommend** change defining which samples must be reanalyzed if the C.V. fails twice. If the intent is to bracket batch, then this would have to go back to the previous C.V.

Comment ID#: WISC_1 **Source of Comments (Name): Alfredo Sotomayor; WI DNR QS Lead on Response (Name): Dave Mendenhall**			
Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	**Comment with Rationale to QS (To Be Filled In By Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONALE (From QS Leader) (Commentor Leave Blank)**
Revision 10.1; Appendix B **Quantitation Limits**: the maximum or minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be quantitated with the confidence level required by the data user.	A maximum quantitation limit, qua limit, is not intuitive. Most analysts understand that above the highest concentration of a calibration standard results are not quantitatively defensible because the region above the standard has not been well characterized, not because above this concentration results are inherently less accurate. However, no matter how well characterized the region between an LOD and the lower LOQ, results by definition cannot be any more certain than what is stated (for the common LOQ at ten times a standard deviation, $\pm$ 30% at the 99% confidence level). I suggest that the definition for "quantitation limits" be changed to what is commonly known as a quatitation limit, and that a definition on calibration range be included to address concerns regarding results calculated above the highest calibration standard.	No Change	Changed in a later revision of the glossary.
	Quantitation Limit: the level or concentration above which quantitative results for an analysis may be obtained with a specified degree of confidence.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
Revision 10.1; Appendix B **Reagent Blank (method reagent blank)** : a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps (Glossary of Quality Assurance Terms, QAMS, 8/31/92).	I think this definition suffers from combining two diagnostic measures into one. Appendix D [see D.1.1 (a) (1)] only recognizes method blanks and therefore the term should be uniquely defined. If a definition for what is commonly known as a reagent blank is needed, it should be segregated from the definition for method blank.	No Change	Method and reagent blank are separate and distinct definitions in this glossary.
	Method Blank: an aliquot of inert matrix that is treated exactly as a sample, including all preparatory and determinative analysis steps, and containing any internal standards and surrogates added to samples, used to determine the contamination and target analyte concentrations contributed by the entire analytical system.		
Revision 10.1; Appendix B **Reference Toxicant**: see D.2.1a	The definition appendix should contain descriptive definitions even when these are found somewhere else in the Standards.	No change.	Changed in a later revision of the glossary.
	Reference Toxicant: a chemical substance or combination of substances used to test the sensitivity of organisms used in whole effluent toxicity testing and to assess the ability of a laboratory to obtain consistent results with a test method.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
Revision 10.1; Appendix B **Requirement**: a translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.	This definition in only superseded in its lack of clarity by the procedure for establishing and determining interelement corrrection factors in the current Method 200.7. (Sorry!) A little surgery and syntax medicine help here.	No change.	Changed in a later revision of the glossary.
	Requirement: a set of quantified or descriptive specifications that enable accomplishing or examining an entity's needs.		
Revision 10.1; Appendix B **Shall**: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (*Style Manual for Preparation of Proposed American National Standards*, American National Standards Institute, eight edition, March 1991).	This definition, in spite of (or maybe because of) its source, smacks the common reader as tautological, or as double speak or double think. If what is specified is a required process, how can alternatives for implementing it be allowed? And if the definition means that conformance with the specification is mandatory, however means are used to achieve that conformance, why not express it thus? Obviously, defining "specification" would help. But note that "shall" is tied in the Standards to more than just specifications. I suspect we are dealing here with two concepts: conformance to a process and conformance to a specification. Whatever is tied to the word "shall" should be mandatory. If a process shall be followed, then following that process is mandatory; if a specification must be attained, then attaining it is mandatory, by whatever means or processes.	No change.	The definition as written is conditional but not inherently perscriptive.

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
	Shall: denotes a process, method, or specification that is mandatory. A mandatory process or method allows no deviation in its execution. A mandatory specification must be attained by whatever process or method enables its attainment.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
Revision 10.1; Appendix B **Spike**: a known mass of target analyte added to a blank sample or subsample;	I do not know for which other quality control purposes a spike might be used. If there are any, these should be specified in the definition. This definition should also be cross-referenced appropriately.	**Spike**: a known mass of target analyte added to a blank sample or subsample; used to determine recovery efficiency or for other quality control purposes. See Matrix Spike and Matrix Spike Duplicate.	Cross referencing follows the established format. The other suggested changes move away from the less

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
	Spike: a known mass or concentration of target analyte added to an inert matrix or a sample that is used to determine recovery efficiency. A spiked sample is formally known as a fortified sample. See Matrix Spike and Matrix Spike Duplicate.		
Revision 10.1; Appendix B **Test Sensitivity/Power**: D.2.4.a	The definition appendix should contain descriptive definitions even when these are found somewhere else in the Standards.	No change	Changed in a later revision of the NELAC Glossary
	Test Sensitivity/Power: the minimum significant difference (MSD), statistically significant at a stated level, between a whole effluent toxicity control and a test concentration.		
Revision 10.1; Appendix C; C.1 (e) For each parameter, compare s and x to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if a non-standard method). If s and x for all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters exceed the acceptance range, the performance is unacceptable for that parameter.	The first time that a non-standard method, or a standard method without published criteria is used in a laboratory, the laboratory cannot have generated any a priori acceptance criteria.	No change	See revision 10.7. The laboratory is required to establish and document QC acceptance criteria. If a method is developed these criteria must be determined and processing of "real " samples may not begin until the criteria are in place.

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
	For each parameter, compare s and x to the corresponding acceptance criteria for precision and accuracy in the test method. When the test method does not contain acceptance criteria the laboratory shall establish them based on previously generated data at the laboratory using the same procedure. When the test method does not contain acceptance criteria and laboratory-generated acceptance criteria is not available, the laboratory shall establish these criteria based on its experience with similar techniques, the experience of other laboratories, or criteria published in methods with similar determinative steps. If s and x for all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters exceed the acceptance range, the performance is unacceptable for that parameter.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
Revision 10.1; Appendix D; D.1.1 (b)	Unlike D.1.1 (a), which contains explicit quality control acceptance criteria, this section lacks any. The general statement at the introduction of Appendix D is not sufficiently strong. I suggest adding individual items addressing this in each of D.1.1 (b) (1); D1.1 (b) (2); and D.1.1 (b) (3).	No change	QC acceptance criteria is required in 5.5.4 Essential QC Procedures The requirement to document QC acceptance criteria in the methods manual is covered in 5.10.1.2

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE (From QS Leader) (Commentor Leave Blank)
	NEW WORDING FOR STANDARD NOT APPLICABLE		
Revision 10.1; Appendix D; D.1.1 (b) (1) **Add as D.1.1 (b) (1) (i)**	The appendix should mention declaring positive control acceptance criteria in this section.	No change	Same as above
	D.1.1 (b) (2) (i) Quality control acceptance criteria for laboratory control samples must be established statistically when this is specified in required methods, or when fixed acceptance criteria is not required or available. When sufficient data is not available to determine statistically derived acceptance criteria, the laboratory shall establish interim criteria until sufficient data is available.		
Revision 10.1; Appendix D; D.1.1 (b) (2) **Add as D.1.1 (b) (2) (i)**	The appendix should mention declaring positive control acceptance criteria in this section.	No change	Same as above
	D.1.1 (b) (2) (i) Quality control acceptance criteria for matrix spikes, segregated by matrix type, must be established statistically when this is specified in required methods, or when fixed acceptance criteria is not required or available. When sufficient data is not available to determine statistically derived acceptance criteria, the laboratory shall establish interim criteria until sufficient data is available.		
Revision 10.1; Appendix D; D.1.1 (b) (3) **Add as D.1.1 (b) (3) (i)**	The appendix should mention declaring positive control acceptance criteria in this section.	No change	Same as above

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	D.1.1 (b) (3) (i) Quality control acceptance criteria for surrogates, segregated by matrix type, must be established statistically when this is specified in required methods, or when fixed acceptance criteria is not required or available. When sufficient data is not available to determine statistically derived acceptance criteria, the laboratory shall establish interim criteria until sufficient data is available.		
Revision 10.1; Appendix D; D.1.3 **Add as D.1.3 (d)**	This section should include a provision for reviewing quality control acceptance criteria to evaluate method performance. I suggest adding this to the end of the section.	No change	Same as above
	d) Quality Control Acceptance Criteria for Positive and Negative Controls – These criteria should be evaluated periodically to determine their continued applicability and to assess trends in method performance.		

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Revision 10.1; Appendix D; D.1.4 (a) An MDL study is not required for any component for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, turbidity or on-line analyses. The detection limits shall be initially determined for the compounds of interest in each test method in a matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the detection limit must be determined in the matrix of interest (see definition of matrix).	The term on-line analysis may require more explanation. I think that by on-line analysis the Standard means continuos on-line monitoring analyses, not continuous flow analyses as in automated wet chemistry. A word here could be added on the appropriateness of the matrix chosen for the MDL to prevent, for instance, that the MDL for a soil extraction be determined using reagent water.	No Change	Rev 10.7 addresses this comment.
	An MDL study is not required for any component for which spiking solutions are not available such as all determinations of solids content (e.g., total suspended solids), pH, color, odor, temperature, dissolved oxygen, turbidity or continuous on-line monitoring analyses. The detection limits shall be determined for the compounds of interest in the matrix of interest or in an inert matrix appropriate for the test method (see definition of matrix). The chosen matrix for the MDL study shall not contain target analytes or interferences at concentrations that would adversely affect the study results.		

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Revision 10.1; Appendix D; D.2.8 (f) New batches of food used for culturing and testing shall be analyzed for toxic organics and metals. If food combinations or recipes are used, analyses shall be performed on the final product upon the use of a new lot of any ingredient. If the concentration of total organic chlorine exceeds 0.15 ug/g wet weight, or the total concentration of organochlorine pesticides plus PCBs exceeds 0.30 ug/g wet weight, or toxic metals exceeds 20 ug/g wet weight, the food must not be used.	This may be unnecessary, if the food manufacturer provides certificates of purity or provides results of analyses that demonstrate the food does not exceed the limits expressed here.		Deferred to Pete DeLisle! [This should be changed to active voice.]
	Revision 10.1; Appendix D; D.2.8 (f) The laboratory shall analyze new batches of food used for culturing and testing for toxic organics and metals, unless the food manufacturer provides assay results for the substances identified below. If food combinations or recipes are used, analyses shall be performed on the final product upon the use of a new lot of any ingredient, unless the ingredient manufacturer has certified the lots as not exceeding the criteria specified here. If the concentration of total organic chlorine exceeds 0.15 ug/g wet weight, or the total concentration of organochlorine pesticides plus PCBs exceeds 0.30 ug/g wet weight, or toxic metals exceeds 20 ug/g wet weight, the food must not be used.		

Comment ID#: , Source of Comments (Name): Alfredo Sotomayor; WI DNR QS Lead on Response (Name):

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE **(From QS Leader)** (Commentor Leave Blank)
	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1 Chapter 5	Items following a colon need to be consistently capitalized or in lower case, whichever convention is followed.		
Revision 10.1; 5.1.b This Standard includes additional requirements for assessing competence or for determining compliance by the organization or accrediting authority granting the recognition (or approval).	Accrediting authorities accredit. NELAP grants recognition to accrediting authorities. This Standard includes additional requirements for assessing competence or for determining compliance by the organization or accrediting authority granting accreditation (or approval).		
Revision 10.1; 5.4.1 The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Standard.	Not all mobile or temporary facilities may need to meet the requirements of this Standard. This is of course now actively being discussed in other committees. Presuming that field measurements can be properly defined, I offer the suggestion here. The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Standard, except when such temporary and mobile facilities are only engaged in providing field measurements.		

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; 5.5.3.4 (f) Correlation of results for different parameters of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).	The concept is good but needs to be clarified. Correlation of results for different but related analytes in a sample (for example, total phosphorus should be greater than or equal to orthophosphate).		
Revision 10.1; 5.6.2 (c) (3) v If i-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically identical results.	Analysts cannot have statistically identical results; their analyses might. If i-iv cannot be performed, analysis of authentic samples with results statistically identical to those obtained by another trained analyst.		
Revision 10.1; 5.6.3 Records of the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see5.6.2c)], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.10.2.1 for chemical testing.	These records should be retained for the same length of time as analytical records, since they may be needed when tracking samples or performing a data audit.		

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Revision 10.1; 5.9.3 Insertion after (c)	**New Wording for Standard** (To Be Filled in By Commentor) Records of the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see5.6.2c)], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.10.2.1 for chemical testing. These records shall be maintained for a minimum of five years. This paragraph is better placed after (e) in 5.9.4.1. NEW WORDING FOR STANDARD NOT APPLICABLE		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE **(From QS Leader)** (Commentor Leave Blank)
Revision 10.1; 5.9.4.2 Instrument Calibration	**New Wording for Standard** (To Be Filled in By Commentor) There is much that is tentative, vague, and objectionable in this whole section. I sympathize with the committee's attempts at serving many conflicting needs. I do agree that the section as written previously needed work because it was inappropriately restrictive or contained dubious criteria. However, the suggested revisions have opted for, in my opinion, undue flexibility. I believe the Standard, as written now, shows a marked imbalance in the level of appropriate direction it offers. For instance, the content and format of the Quality Assurance Manual is specified in exquisite detail, and quantitative acceptance criteria has been devised for negative controls in Appendix D. But with the single most important mean of ensuring the validity of quantitative results, the Standard, as written now, shies away from even suggesting default minimum criteria. One of the reasons for the current proliferation of calibration methods, algorithms, and options is that definitive and sensible criteria are difficult to come-by or not easy to formulate. However the QS Committee should be up to this task. If not, who else will be? Leaving this up to simply documenting a system works well for non-quantitative decision-making, but is not appropriate for the principal mean of translating original observations into		

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Revision 10.1; 5.9.4.1; This standard does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s). The following items are essential elements of initial instrument calibration…	**New Wording for Standard** (To Be Filled in By Commentor) NEW WORDING FOR STANDARD NOT APPLICABLE I do not see where in this section the essential elements for the **selection** of an appropriate calibration technique are specified. Many of the requirements in this section address documenting and traceability of the calibration technique already chosen. It would be presumptuous of me to suggest language to address all of this—this would take an inordinate amount of time and as I have suggested above, may be the work of a group not of an individual. Criteria for **selection** of an appropriate technique should include among others: an understanding of the fundamental relationship expected between a detector's response and concentration, whether this be empirical or obeying an established physical or chemical law; basic rules for **selecting** the number of standards to establish a calibration function; and minimum acceptability criteria when other sources do not specify any. NEW WORDING F OR STANDARD NOT APPROPRIATE		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE **(From QS Leader)** (Commentor Leave Blank)
	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; 5.9.4.2.1 (b) Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor.	The mathematical functions used to translate raw data into concentration should be retained as well. This is certainly implied in the wording, but in my experience, being explicit here cannot hurt.		
	Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, concentration and response, calibration curve, response factor, or unique equations or coefficients used to reduce instrument responses into concentrations.		
Revision 10.1; 5.9.4.2.1 (e) Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient and relative percent difference.	As you can gather from my previous comments, I am in favor of specifying minimum acceptance criteria. In the meantime, I offer the following suggestion. Criteria for the acceptance of an initial calibration must be established, e.g., correlation coefficient and relative percent difference. The criteria employed must be appropriate to the calibration technique chosen for generating the initial instrument calibration.		

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; 5.9.4.2.1 (f) Results of samples not bracketed by initial calibration standards must be reported as having less certainty, e.g. defined qualifiers or flags or explained in the case narrative.	The Standard should encourage diluting sample responses that exceed the top calibration standard, and use qualification as a last recourse. Results of samples with responses below the lowest calibration standard must be reported as having less certainty. Results of samples that exceed the response of the highest calibration standard must be diluted if results are to be quantitative or must be reported as having less certainty. All qualifiers or flags indicating diminished certainty must be explained in laboratory reports or case narratives.		
Revision 10.1; 5.9.4.2.1 (h) Calibration standards must include concentrations at or below the regulatory limit/decision level, if these limits are known by the laboratory.	The last clause of this sentence promotes ignorance. I suspect most accrediting authorities will publish reporting, decision, and action limits that accredited laboratories will need to meet for regulatory work. For non-regulatory work, knowing a limit is not an issue. Using standards below the quantitation limit compromises the accuracy of the calibration function. Since results below the lowest calibration standard will be duly noted, this requirement can be safely tempered.		

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	New Wording for Standard (To Be Filled in By Commentor) Instrument calibrations must include standards at concentrations at or below regulatory limits or decision levels, when using these concentrations does not compromise the accuracy of quantitations.		
Revision 10.1; 5.9.4.2.1 (i) The minimum number of concentration points for performing an initial instrument calibration must be specified by the analytical method or if not specified by the method then the laboratory must have a standard operating procedure for determining the appropriate number of points for establishing the initial instrument calibration.	My position notwithstanding, if the Committee insists on documentation instead of specifying selection criteria, then a word about the adequacy of the procedure chosen might be appropriate.		
	The minimum number of standard concentration points for performing an initial instrument calibration must be specified by the analytical method or if not specified by the method, then the laboratory must have a standard operating procedure for determining the appropriate number of points for establishing the initial instrument calibration. The number of standard points chosen for performing an initial instrument calibration must be appropriate for the quantifying detector and the calibration function, algorithm or reduction technique selected.		

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; 5.9.4.2.2 The following items are essential elements of continuing instrument calibration verification.	As you might have predicted, I have objections similar to what I stated on 5.9.4.2.1 for this entire section. Some detailed comments follow. NEW WORDING FOR STANDARD NOT APPLICABLE.	No Change	
Revision 10.1; 5.9.4.2.2 (b) A continuing calibration check must be repeated at the beginning and end of each analytical batch.	The sentence as written could lead some to believe that each of these checks must be replicated. Continuing calibration checks must be performed at the beginning and at the end of each analytical batch.	No Change	The suggested verbiage could lead to the question "How many checks?"
Revision 10.1; 5.9.4.2.2 (c) In each analytical batch the calibration verification checks must include concentrations at the lowest and highest concentration of the initial instrument calibration. As an option, the lowest regulatory limit associated with the samples may be substituted for the low concentration.	This may not be the most defensible way of verifying an initial calibration. Consider that this language allows the lowest point in an initial calibration to be below the limit of quantitation, and in this region, by definition, the accuracy of quantitations cannot be ensured. Moreover, when non-linear calibration techniques are selected, the concentration of at least one verifying standard should be strategically chosen to test areas of a curve where departures from linearity are evident. Once again, I believe these criteria should be developed. But in the meantime, I suggest the following.	No Change	See current revision

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	New Wording for Standard (To Be Filled in By Commentor) In each analytical batch the concentration of the calibration verification checks must be chosen to conclusively verify the validity of the initial instrument calibration over its entire range. For linear calibration functions, a single standard concentration in the mid-range of the calibration range may be sufficient to perform this validation. For non-linear calibration functions, or segmented fits, at least two standards must be chosen to verify the validity of an initial instrument calibration. The number of standard concentrations chosen for verifying non-linear calibration functions or segmented fits must check the initial instrument calibration in non-linear regions or in more than one segment, respectively. Additionally, when compliance with regulations require verifying accuracy about an established limit, the accuracy of the initial instrument calibration at or about this limit may need to be tested independently or as part of a continuing calibration verification check.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor) **New Wording for Standard** (To Be Filled in By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE **(From QS Leader)** (Commentor Leave Blank)
Revision 10.1; 5.9.4.2.2 (d) Sufficient raw data records must be retained to permit reconstruction of the continuing calibration verification, e.g., test method, instrument analysis date, each analyte name, concentration and response, calibration curve or response factor.	I am suggesting similar language here to what I proposed in 5.9.4.2.1 (b) and adding that the checks must be traceable to the initial calibration being verified.	Sufficient raw data records must be retained to permit reconstruction of the continuing calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve, response factor, or unique equations or coefficients used to reduce instrument responses into concentrations. Continuing calibration verification records must explicitly connect the continuing verification data to the initial instrument calibration verified.	Change accepted. Adds flexibility and provides stronger links between the initial calibration and the continueing calibration verification(s)

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	New Wording for Standard (To Be Filled in By Commentor) Sufficient raw data records must be retained to permit reconstruction of the continuing calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve, response factor, or unique equations or coefficients used to reduce instrument responses into concentrations. Continuing calibration verification records must explicitly connect the continuing verification data to the initial instrument calibration verified.		
Revision 10.1; 5.9.4.2.2 (e) Criteria for the acceptance of a continuing instrument calibration verification must be established, e.g. relative percent difference.	Once again, I am in favor of specifying minimum acceptance criteria. In the meantime, I offer the following suggestion. Criteria for the acceptance of a continuing instrument calibration must be established, e.g., correlation coefficient and relative percent difference. The criteria employed must be appropriate to verifying the calibration technique chosen for generating the initial instrument calibration.	No Change	See current revision

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; 5.9.4.2.2 (f) (ii) When the acceptance criteria for the continuing calibration verification check are exceeded low, i.e., low bias, these sample results may be reported if there are associated samples that exceed a maximum regulatory limit/decision level. Otherwise, the samples affected by the unacceptable check shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.	Because exceeding a regulatory limit can often result in enforcement actions or contested cases, data associated with such exceedances must be highly defensible. Failing a calibration verification check on the low side jeopardizes the defensibility of the calibration. Consider also that any potential contamination that would invalidate the exceedance or that would result in qualifying the corresponding analytical result [see D.1.1 (a)] would not necessarily be discernible from method or reagent blank results when calibrations are biased low. When the acceptance criteria for the continuing calibration verification check are exceeded low, i.e., low bias, samples affected by the unacceptable check shall be reanalyzed after a new calibration curve has been established, evaluated and accepted, unless the associated samples exceed a maximum regulatory limit or decision level, and the affected results can be accepted as qualitative.	No Change	See current revision
Revision 10.1; 5.10.4 (a) The laboratory shall establish Standard Operating Procedures to ensure that the reported data are free from transcription and calculation errors.	Data verification should also include verifying data reduction formulas or algorithms. Checking for calculation errors may imply that, but I would err on being explicit here.	No Change	See current revision

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	New Wording for Standard (To Be Filled in By Commentor) The laboratory shall establish Standard Operating Procedures to ensure that the reported data are free from transcription and calculation errors, and that data reduction formulas and algorithms correctly translate analytical responses into concentrations.		
Revision 10.1; 5.12.2 (a) All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client. NELAP-related records shall be available to the accrediting authority.	The last sentence of section 5.0 states: "All items identified in this chapter shall be available for an on-site inspection or data audit." The last sentence of 5.12.2 (a) is thus unnecessary. But if, if this item is trying to explicitly limit the ability of auditors to request some records, then 5.0 will need to be changed as well. Consider what follows as a possible alternative. All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client. All records identified in this chapter shall be available to official representatives of accrediting authorities who shall give due consideration to claims of confidential business information, as detailed in Chapter 3.	All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.	Last sentence redundant.
Revision 10.1; 5.12.3.1 (j) Method performance criteria and expected quality control requirements;	I am not sure what "expected quality control requirements" means in this context. Method and expected quality control performance criteria;	No Change	See current revision

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; 5.12.3.2 (a) All original raw data, whether hard copy or electronic, for calibrations, samples, and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);	This is very good. To make it better, and to enable checking what is nicely specified later in 5.12.3.2 (b), I suggest what follows. All original raw data, whether had copy or electronic, for calibrations, samples, and quality control measures, including responses used to obtain concentrations, analysts work sheets and data output records (chromatogram, strip charts, and other instrument response readout records);	No Change	See current revision
Revision 10.1; 5.12.3.2 (h) Data review and cross checking	This item needs a change to improve its sense and to maintain parallel structure with the other items in the section. “Cross checking” may need to be defined if it means here something other than its common sense. Results of data review, verification and cross checking exercises.	Results of data review, verification and cross checking exercises.	Improves consistency of section

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; Appendix B **Detection Limit**: the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence.	I am not certain what is meant here by "a single measurement", but perhaps you have discussed this ad nauseam during annual and interim meetings. Does this exclude from the definition any estimates made by replicate measurements? Is it meant to legitimize an estimate based on the signal to noise ratio of a very low level standard? See definition for Limit of Detection. NEW WORDING FOR STANDARD NOT SUGGESTED.	No Chenge	See current revision
Revision 10.1; Appendix B **Initial Demonstration of Capability**: procedure to establish the ability of the laboratory to generate acceptable accuracy and precision.	These need to be analyte and method specific and need to be performed before actual samples are analyzed. **Initial Demonstration of Capability**: procedure to establish the ability of an analyst to generate acceptable accuracy and precision with a specified method, before that analyst is able to analyze client samples.	No Change	See current revision
Revision 10.1; Appendix B **Internal Standard**: a known amount of standard added to a test portion of a sample and carried through the entire measurement process as a reference for evaluating and controlling the precision and bias of the applied analytical test method.	This definition misses the point that at least in chemistry, internal standards are used to adjust the concentration of concurrently analyzed compounds. Save for the anomalous Method 525.2, internal standards are not carried through the entire measurement process. They are principally quantitative tools and secondarily indicators of system bias or lack of sensitivity. **Internal Standard**: a pure analyte added	**Internal Standard**: a known amount of standard added to a test portion of a sample and carried through the entire measurement process as a reference for determining the target analyte concentration and for evaluating and controlling the precision	More correct and specific.

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; Appendix B **Limit of Detection (LOD)**: the lowest concentration level that can be determined by a single analysis and with a defined level of confidence to be statistically different from a blank (Analytical Chemistry, 55, p.2217, December 1983, modified) See also Method Detection Limit.	I was familiar with the Analytical Chemistry citation and checked it to see if it mentioned anything about a "single analysis" that could clarify this for me. What I found suggests this is one of the modifications you have made to this definition. The article states: "The limit of detection (LOD) is defined as the lowest concentration level that can be determined to be statistically different from a blank." I prefer the simplicity of this definition. Reference number 25 in this article, Analytical Chemistry, V.55, p.713 A, June 1983, deals with the IUPAC definition: "…the smallest measure…that can be detected with reasonable certainty for a given analytical procedure". Whatever the reasons for making these modifications, this definition should be the same as that for detection limit. Alternatively, you could send the reader of one definition to the other by proper cross-referencing. NEW WORDING FOR STANDARD NOT SUGGESTED	No Chenge	

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Revision 10.1; Appendix B **Quantitation Limits**: the maximum or minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be quantitated with the confidence level required by the data user.	**New Wording for Standard** (To Be Filled in By Commentor) A maximum quantitation limit, qua limit, is not intuitive. Most analysts understand that above the highest concentration of a calibration standard results are not quantitatively defensible because the region above the standard has not been well characterized, not because above this concentration results are inherently less accurate. However, no matter how well characterized the region between an LOD and the lower LOQ, results by definition cannot be any more certain than what is stated (for the common LOQ at ten times a standard deviation, $\pm$ 30% at the 99% confidence level). I suggest that the definition for "quantitation limits" be changed to what is commonly known as a quatitation limit, and that a definition on calibration range be included to address concerns regarding results calculated above the highest calibration standard. **Quantitation Limit**: the level or concentration above which quantitative results for an analysis may be obtained with a specified degree of confidence.		

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; Appendix B **Reagent Blank (method reagent blank)** : a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps (Glossary of Quality Assurance Terms, QAMS, 8/31/92).	I think this definition suffers from combining two diagnostic measures into one. Appendix D [see D.1.1 (a) (1)] only recognizes method blanks and therefore the term should be uniquely defined. If a definition for what is commonly known as a reagent blank is needed, it should be segregated from the definition for method blank. **Method Blank**: an aliquot of inert matrix that is treated exactly as a sample, including all preparatory and determinative analysis steps, and containing any internal standards and surrogates added to samples, used to determine the contamination and target analyte concentrations contributed by the entire analytical system.		
Revision 10.1; Appendix B **Reference Toxicant**: see D.2.1a	The definition appendix should contain descriptive definitions even when these are found somewhere else in the Standards. **Reference Toxicant**: a chemical substance or combination of substances used to test the sensitivity of organisms used in whole effluent toxicity testing and to assess the ability of a laboratory to obtain consistent results with a test method.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE **(From QS Leader)** (Commentor Leave Blank)
	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; Appendix B **Requirement**: a translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.	This definition in only superseded in its lack of clarity by the procedure for establishing and determining interelement corrrection factors in the current Method 200.7. (Sorry!) A little surgery and syntax medicine help here. **Requirement**: a set of quantified or descriptive specifications that enable accomplishing or examining an entity's needs.		
Revision 10.1; Appendix B **Shall**: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (*Style Manual for Preparation of Proposed American National Standards*, American National Standards Institute, eight edition, March 1991).	This definition, in spite of (or maybe because of) its source, smacks the common reader as tautological, or as double speak or double think. If what is specified is a required process, how can alternatives for implementing it be allowed? And if the definition means that conformance with the specification is mandatory, however means are used to achieve that conformance, why not express it thus? Obviously, defining "specification" would help. But note that "shall" is tied in the Standards to more than just specifications. I suspect we are dealing here with two concepts: conformance to a process and conformance to a specification. Whatever is tied to the word "shall" should be mandatory. If a process shall be followed, then following that process is mandatory; if a specification must be attained, then attaining it is mandatory, by whatever means or processes.		

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	New Wording for Standard (To Be Filled in By Commentor) **Shall**: denotes a process, method, or specification that is mandatory. A mandatory process or method allows no deviation in its execution. A mandatory specification must be attained by whatever process or method enables its attainment.		
Revision 10.1; Appendix B **Spike**: a known mass of target analyte added to a blank sample or subsample; used to determine recovery efficiency or for other quality control purposes.	I do not know for which other quality control purposes a spike might be used. If there are any, these should be specified in the definition. This definition should also be cross-referenced appropriately. **Spike**: a known mass or concentration of target analyte added to an inert matrix or a sample that is used to determine recovery efficiency. A spiked sample is formally known as a fortified sample. See Matrix Spike and Matrix Spike Duplicate.		
Revision 10.1; Appendix B **Test Sensitivity/Power**: D.2.4.a	The definition appendix should contain descriptive definitions even when these are found somewhere else in the Standards. **Test Sensitivity/Power**: the minimum significant difference (MSD), statistically significant at a stated level, between a whole effluent toxicity control and a test concentration.		

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	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; Appendix C; C.1 (e) For each parameter, compare s and x to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if a non-standard method). If s and x for all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters exceed the acceptance range, the performance is unacceptable for that parameter.	The first time that a non-standard method, or a standard method without published criteria is used in a laboratory, the laboratory cannot have generated any a priori acceptance criteria.		
	For each parameter, compare s and x to the corresponding acceptance criteria for precision and accuracy in the test method. When the test method does not contain acceptance criteria the laboratory shall establish them based on previously generated data at the laboratory using the same procedure. When the test method does not contain acceptance criteria and laboratory-generated acceptance criteria is not available, the laboratory shall establish these criteria based on its experience with similar techniques, the experience of other laboratories, or criteria published in methods with similar determinative steps. If s and x for all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters exceed the acceptance range, the performance is unacceptable for that parameter.		

Standard Rev.# SECTION# and QS Standard Narrative (To Be Filled In By Commentor)	Comment with Rationale to QS (To Be Filled In By Commentor)	QS Leader Provided Proposed Change (Commentor Leave Blank)	RATIONALE **(From QS Leader)** (Commentor Leave Blank)
	New Wording for Standard (To Be Filled in By Commentor)		
Revision 10.1; Appendix D; D.1.1 (b)	Unlike D.1.1 (a), which contains explicit quality control acceptance criteria, this section lacks any. The general statement at the introduction of Appendix D is not sufficiently strong. I suggest adding individual items addressing this in each of D.1.1 (b) (1); D1.1 (b) (2); and D.1.1 (b) (3).		
Revision 10.1; Appendix D; D.1.1 (b) (1) **Add as D.1.1 (b) (1) (i)**	NEW WORDING FOR STANDARD NOT APPLICABLE The appendix should mention declaring positive control acceptance criteria in this section. D.1.1 (b) (2) (i) Quality control acceptance criteria for laboratory control samples must be established statistically when this is specified in required methods, or when fixed acceptance criteria is not required or available. When sufficient data is not available to determine statistically derived acceptance criteria, the laboratory shall establish interim criteria until sufficient data is available.		
Revision 10.1; Appendix D; D.1.1 (b) (2) **Add as D.1.1 (b) (2) (i)**	The appendix should mention declaring positive control acceptance criteria in this section.		

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	New Wording for Standard (To Be Filled in By Commentor) D.1.1 (b) (2) (i) Quality control acceptance criteria for matrix spikes, segregated by matrix type, must be established statistically when this is specified in required methods, or when fixed acceptance criteria is not required or available. When sufficient data is not available to determine statistically derived acceptance criteria, the laboratory shall establish interim criteria until sufficient data is available.		
Revision 10.1; Appendix D; D.1.1 (b) (3) **Add as D.1.1 (b) (3) (i)**	The appendix should mention declaring positive control acceptance criteria in this section. D.1.1 (b) (3) (i) Quality control acceptance criteria for surrogates, segregated by matrix type, must be established statistically when this is specified in required methods, or when fixed acceptance criteria is not required or available. When sufficient data is not available to determine statistically derived acceptance criteria, the laboratory shall establish interim criteria until sufficient data is available.		
Revision 10.1; Appendix D; D.1.3 **Add as D.1.3 (d)**	This section should include a provision for reviewing quality control acceptance criteria to evaluate method performance. I suggest adding this to the end of the section.		

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Revision 10.1; Appendix D; D.1.4 (a) An MDL study is not required for any component for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, turbidity or on-line analyses. The detection limits shall be initially determined for the compounds of interest in each test method in a matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the detection limit must be determined in the matrix of interest (see definition of matrix).	**New Wording for Standard** (To Be Filled in By Commentor) d) <u>Quality Control Acceptance Criteria for Positive and Negative Controls</u> – These criteria should be evaluated periodically to determine their continued applicability and to assess trends in method performance. The term on-line analysis may require more explanation. I think that by on-line analysis the Standard means continuos on-line monitoring analyses, not continuous flow analyses as in automated wet chemistry. A word here could be added on the appropriateness of the matrix chosen for the MDL to prevent, for instance, that the MDL for a soil extraction be determined using reagent water.		

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Revision 10.1; Appendix D; D.2.8 (f) New batches of food used for culturing and testing shall be analyzed for toxic organics and metals. If food combinations or recipes are used, analyses shall be performed on the final product upon the use of a new lot of any ingredient. If the concentration of total organic chlorine exceeds 0.15 ug/g wet weight, or the total concentration of organochlorine pesticides plus PCBs exceeds 0.30 ug/g wet weight, or toxic metals exceeds 20 ug/g wet weight, the food must not be used.	**New Wording for Standard** (To Be Filled in By Commentor) An MDL study is not required for any component for which spiking solutions are not available such as all determinations of solids content (e.g., total suspended solids), pH, color, odor, temperature, dissolved oxygen, turbidity or continuous on-line monitoring analyses. The detection limits shall be determined for the compounds of interest in the matrix of interest or in an inert matrix appropriate for the test method (see definition of matrix). The chosen matrix for the MDL study shall not contain target analytes or interferences at concentrations that would adversely affect the study results. This may be unnecessary, if the food manufacturer provides certificates of purity or provides results of analyses that demonstrate the food does not exceed the limits expressed here.		

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	New Wording for Standard (To Be Filled in By Commentor) Revision 10.1; Appendix D; D.2.8 (f) The laboratory shall analyze new batches of food used for culturing and testing for toxic organics and metals, unless the food manufacturer provides assay results for the substances identified below. If food combinations or recipes are used, analyses shall be performed on the final product upon the use of a new lot of any ingredient, unless the ingredient manufacturer has certified the lots as not exceeding the criteria specified here. If the concentration of total organic chlorine exceeds 0.15 ug/g wet weight, or the total concentration of organochlorine pesticides plus PCBs exceeds 0.30 ug/g wet weight, or toxic metals exceeds 20 ug/g wet weight, the food must not be used.		